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SUMMARY

Introduction/relevance to the Symposium

Accessing the medullary space of the bone, offers a rapid, effective, and reasonably foolproof alternative to IV access. Newly introduced adult intraosseous (IO) technologies have been suggested as one means to improve success rate of emergency vascular access. The National Academy of Sciences' Institute of Medicine Report recommends IO infusion as the preferred initial vascular route for combat casualty care.

Rationale

This review compares IO access devices, with a focus on the clinical record of the five FDA approved adult IO devices in use today and of one in advanced development.

Description of methods employed and results obtained

Published adult IO case reports, studies and clinical trials were identified and suggest utility and effectiveness as well as documenting complication rates. A user survey of American and British military medics and corpsmen and US paramedics is underway.

Adult IO Devices: The Jamshidi IO access needle is similar to the sturdy trocared needles first used in WWII, and commercially available since the late 1960's. Two sternal access devices were developed by the Dutch military and the US Army. The adult Sur-Fast (Cook Medical) IO needle is a one-piece 12-gauge screw/cutting tipped needle with a side port for infusion and a handle allowing insertion. More recently a device to safely insert a 16-gauge IO port into the sternum (FAST-1, Pyng Medical) and a device to inject a trocared needle into the tibia (BIG, Wais Med, Ltd) achieved FDA approval. New IO devices being developed

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include the EZ-IO (Vidacare), which is the first battery powered IO device that has received FDA approval in 2004.

Case Studies and Controlled Trials: Several positive case reports and trials of adult IO have recently been reported, but most have had support and participation from IO manufactures. The few independent reports suggest effectiveness, and interestingly, seem to establish equivalence of different devices. Notably the Army conducted a special operations medic user study comparison of IO access using FAST-1, BIG, Sur-Fast and Jamshidi in human cadavers. No device was a clear favorite, all had similar success rates (94-97%) and access times (70-114 seconds) suggesting that training and experience may be a larger factor in success than the device. The first 50 uses of FAST-1 by practicing paramedics and emergency physicians reported an 84% success rate, mean access time of 77 seconds and maximum flow rates of 80 –150 ml/min via gravity or pressurized bag; most failures were attributed to obesity. US regulatory approval of IO devices is based on the 510k process, which means that the FDA has ruled that the different IO devices are substantially equivalent. Complications of IO access have been extensively reviewed and are similar to those of IV access with a few exceptions to be presented. An ongoing survey of adult IO use will report on the operational experiences of both civilian and military medics with currently available adult IO devices.

Conclusions

IO vascular access devices appear to fill a special need for combat casualty care, but independently funded cohort analyses and randomized controlled trials are needed to fully evaluate efficacy and safety.

PURPOSE

The purpose of this communication is to review the availability, acceptance and effectiveness of intraosseous (IO) infusion devices to provide rapid vascular access for the administration of resuscitation fluids and drugs in time-critical emergency scenarios, in both institutional (hospital) and pre-hospital settings and to suggest future directions for such technology. Emphasis in this communication will be on IO use in adults.

INTRODUCTION

History of IO vascular access and IO needles: The scientific background on the use of the intraosseous vascular access route dates to at least the 1920's when Cecil Drinker reported that fluids, dyes and blood administered into bone marrow rapidly entered the circulation (Drinker et al., 1922). Prior to World War II, in a series of elegant experiments in England, Tocantins and O'Neill (1940, 1941) demonstrated, first in animals and then in human patients, the effective use of intraosseous vascular access and infusion for treatment. Henning (1940) used the sternal IO route to transfuse a patient with granulocytopenia. During WW II, IO access was used to deliver fluid and blood in a number of case reports and reviews, most often in a hospital environment (Bailey, 1944; Quilligan and Turkel, 1946). The culmination of this work was one of the earliest reports of resuscitation by a 'first responder' and the use of IO for prehospital combat casualty care. A B-29 bomber crew revived a seriously injured and bleeding crewmember with collapsed veins which prevented starting an IV. During the long mission over Japan, the crew established IO vascular access and successfully infused sufficient plasma into the sternal circulation to allow subsequent venous cannulation and recovery from shock and eventual long term survival. (Detroit News, March 13 1944). While it was not stated in the article, a variation of a Turkel needle was probably used, as Dr. Turkel had published several reports of his new trocared IO needle with adjustable depth guard for sternal access. (Turkel, 1944) Such early reports in hospitals and this dramatic story of prehospital delivery of life saving resuscitation emphatically underscored the potential for the IO route to provide prompt vascular access in time-critical situations under less than ideal conditions.

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After WW II, in the 1950's through the 1970's, the use the IO route greatly diminished and there were few reports in the literature. Peace seemed to remove the stimulus for its use. In 1950's, there were no paramedics, no prehospital care, no emergency physicians and few emergency protocols that required IV drug therapy. IV vascular access was mainly used for infusion of blood and plasma for treatment of hemorrhage or anemia. The wide acceptance of crystalloid therapy to treat hemorrhage was just beginning to be developed. Additionally, plastic catheters were just beginning to be used and with their widespread acceptance, IV therapy became the standard of care for in hospital use for a growing number of indications. IVs were mostly started by doctors and almost exclusively used in hospitals.

Table 1 lists IO needles use for adult vascular access and briefly described in the text.

Table 1 Adult Intraosseous Vascular Access Devices (*commercially available)

Device, Reference	Source	Design & comments	Insertion Site
Trocared needle Tocantins, 1940	George Pilling & Sons;	4 part trocared needles with wing handle, ball guard to adjust length	sternum
Trocared needles Paper 1942	Becton Dickerson	2 part trocared needle. Used by military	sternum
Trocared needle, Bailey, 1944	Whilen Brothers, England	Trocared needle with wing handle apparently used in London Blitz	sternum
Turkel Needles Quilligan, 1946	Unknown	Stylet-trephened needle for tibia, femur or sternum. Steel reusable.	Tibia, & Sternum
IO Device Dankmeijer, 1975	Dutch Navy	Screw-threaded needle. Used for cold water rescue by Dutch Navy	Sternum,
Jamshidi needle*, Glaeser, 1993	Baxter Health Care	Trocared needle adjustable length, disposable	Tibia, Ilium Sternum
SAVE, Halvorsen, 1990	US Army & University of California	Screw threaded needle, not commercialized	Sternum
SurFast*, LaSpada, 1995	Cook Critical Care	Screw-threaded needle with chisel point & removable handle	Tibia
FAST-1*, Macnab, 2002	Pyng Medical, Vancouver, British Columbia	Rapid manual insertion, corrects for skin thickness	Sternum
B.I.G.* Waisman, 1997	Waismed Ltd, Israel	Spring loaded injectable needle, rapid insertion	Tibia
EZ IO, FDA approval 2004	Vidacare San Antonio, Texas	Battery-powered drill; semi- Permanent, controlled insertion	Tibia
FirstMed in development	Resuscitation Solutions, Inc. Galveston	Spring-loaded auto-injector; single 2–ml dose, disposable	Sternum or Tibia



It was in the 1970's that the new specialty of emergency medicine was emerging and physicians like William Spivey rediscovered the IO route (Spivey, 1985) and applied it to a specific ER problem – delays and failure rates for emergency fluid and drug delivery for pediatric emergencies. (McNamara et al., 1986) The late 1970's through the early 1990's saw a flurry of animal research articles showing pharmacokinetic equivalence between IO and IV with several drugs (Shoor et al., 1979; Cameron et al, 1989; Orlowski et al, 1990; Dubick et al, 1992; Neufeld et al, 1993; Kentner et al., 1999) and several reviews emerged on the use of IO. During this time period, the IO technique was introduced to paramedics who used the Pediatric IO needles made by Cook Critical Care as well as the Jamshidi needles, which were disposable and similar in design to the reusable trocared needles of Paper and Bailey needles (Papper, 1942; Bailey 1944; Glaeser, 1993). Reviews frequently mentioned that IO access could be used in adults and adult IO use was sometimes reported in a few cases (Iserson, 1989), but the focus remained on pediatric emergencies. The Dutch Navy was the first armed service since World War II to adopt and use an IO needle and they used a unique self starting screw tip hollow needle for sternal access in the late 1970's (Dankmeijer, 1970). This device was employed as part of the emergency equipment on rescue helicopters for starting vascular access in victims of hypothermia. The US Army and University of California collaborated on another independently designed sternal access vascular entry (SAVE) device which also had a self tapping screw and a stabilization plate and unique design to stop advancement once the marrow was reached (Halvorsen, 1990; Runyon, 1993).

The SAVE technology (cf. above) was licensed to Pyng Medical (Vancouver, British Columbia, Canada) who studied the limitations of sternal access with standard needles. Pyng eventually adopted and commercialized another design and introduced the first of the new breed of sternal needles, the <u>FAST-1</u> vascular access system. The FAST-1 was designed to deliver more rapid and safer sternal infusion based on an ingenious design that allowed rapid manual insertion as a series/circle of outer needles that stop on the bone surface, thus allowing the placement of the central IO needle a fixed distance beyond the depth of the outer needles. The short IO needle, with attached tubing, would be placed at the correct depth regardless of skin thickness. The FAST-1 system also provides a patch to mark the insertion site and a hard plastic dome to protect the inserted catheter.

Another novel technology to rapidly gain vascular access, focused on tibial access using a spring loaded injector, is the <u>Bone Injection Gun (B.I.G.</u>, Waismed, Israel) that has been used in several studies and trials (see Table 3). And recently, a new battery powered IO vascular access device has been described (EZ IO, VidaCare, San Antonio, TX). This unit is a hand-held, battery-powered drill for quickly placing IO devices. The EZ IO has recently received 510k approval from the U.S. Food and Drug Administration and should be appearing commercially in the near future. Such an approach may provide greater success at access and also provide a needle more tightly attached to the bone than manually inserted devices. For the military the weight and size of a battery powered driver is a discouragement for deployment with field medics.

Intraosseous infusion is also entering the autoinjectors arena. One such device, designed to put automated IO drug delivery in the hands of a wide variety of first responders, is FirstMed (Resuscitation Solutions, Inc., Galveston, TX). FirstMed is a single use, spring-loaded auto-injector capable of administering 2-ml of emergency drugs in time-critical situations. This device is still in development.

Surveys of IO use

Several surveys have explored the familiarity with or acceptance of IO device use within the medical community. Overwhelmingly, the emphasis has been on pediatric use. Therefore, the information obtained from such surveys cannot be extrapolated easily to the use of IO devices in an adult population. Major surveys devoted to the IO application are presented in Table 2.

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Table 2 Surveys of IO vascular access

Authors	Devices	Respondents	Conclusions
Spivey, 1988	Tibia sternum	303 respondents Emergency & Pediatric Depts. Medical Schools	808 IO cases cardiac arrest, dehydration , shock & seizures – 82% success
Zimmerman 1989	Pediatric tibia	133 aeromedical programs	~80% success; 69% knew of, but did not consider IO
Lavis, 2000	Jamshidi	157 Emergency Consultants, Gr. Britain	Adult IO use is not taught (11%) or widely used (7%)
Kramer, Bruttig, 2004	All adult	EMTs, military medics, physicians	On-going survey

William Spivey conducted an extensive postal survey sent to over 1,193 physicians of 898 medical schools in 76 countries and presented the results of the survey at the 2nd International Conference on Emergency Medicine. He had 303 respondents who reported on 808 cases over a two-year period of the mid-1980's. In the US and Canada, IO access was most often used to treat cardiac arrest with drug delivery, while in the Middle East and South America, IO access was used mostly to deliver fluids for dehydration and shock. Overall success rates were calculated to be 82%. The major complications were cellulitis and osteomyelitis and were reported to have an incidence rate of 1.3%.

In a survey of aeromedical evacuation programs conducted by personnel of the University of Wisconsin (Zimmerman et al., 1989), regarding adoption of intraosseous infusion as part of pre-hospital care, 69.2% (of 133 programs) had not implemented IO access nor were they considering implementation, 13.5% had used IO access and 15.8% had not used it but had implemented an in-service training program for its use. Of the programs using or considering use of IO access (39 programs), seven programs restricted IO insertion to physicians while thirty-two programs permitted insertion of IO devices by nurses or paramedics. Of the programs using or considering IO access, half of the programs would use it after 5 minutes of attempting to obtain an IV access. Of the programs that were using IO access, 80% of the attempted insertions were successful, with few and minor complications.

Lavis et al. (2000) conducted a postal survey to determine acceptance and use of IO for rapid vascular access in adults. The survey was sent to 559 emergency departments, with an apparent response of 332 departments. "Seventy four per cent of respondents were aware that intraosseous infusion could be used in adult resuscitation, while only seven per cent used the technique. All (100%) were involved with training their medical staff and 11% said they taught the technique for use in adults. The majority of respondents were accredited in at least one of the adult resuscitation training courses." The authors concluded that IO use was infrequently taught and made a plea for greater teaching effort.

In a recent literature survey (Kahn & Kissoon, 2000) regarding IO use in pediatric patients, the authors categorize their findings for complications into 5 areas (extravasation and compartment syndrome; bone marrow and fat embolism; localized cellulitis, subcutaneous abscess and osteomyelitis; iatrogenic bone



fracture; injury to epiphysis) with the two complications of any concern being extravasation and compartment syndrome. Infection was considered less of a concern after 1980 due to better aseptic technique. The authors emphasize that many complications are the result of poor technique and recommended more and better training.

With the advent of renewed interest for IO devices as a viable option for rapid access to the vascular space, and increasing concerns about terrorism, mass casualty situations, combat casualty care, and other forms of emergency medicine directed at adult populations, a survey focused on IO use in adult populations is warranted. Also, due to the recent comments voiced by in the ACLS textbook, namely that IO access has limited evidence based publications, a more up-to-date and comprehensive survey of IO use, emphasizing benefit and the documentation of complications is warranted (ACLS reference textbook, 2003). Such information may provide the preliminary data to justify a call for clinical trials to more rigorously evaluate any benefits of IO access versus IV access or one IO regimen versus another. Therefore, our research group (Kramer, Bruttig & Wu) is currently launching a web-based survey of IO use in adults, by civilian and military emergency medical personnel, in order to address some of these issues.

Clinical Trials and Case Reports

There have been several small clinical trials for IO use in adults, and the scientific literature also contains several case reports, especially from 1965 forward to today. IO use has been employed in fits and starts, in the adult community, for over 60 years, yet there is reluctance to take full advantage of the benefits of IO access as a first choice treatment modality. Most often, IO access is attempted only after repeated attempts at the more traditional forms of IV access (venipuncture and venous cutdown). Reviews usually suggested the utility of IO access in adults, but until the development of special adult needles, adult IO use was rare. Table 3 summarizes some of the literature documenting studies and use of IO access in adults.

Iserson (1989) conducted a study to determine the utility of IO in adults. They studied 22 patients between 36 and 84 years (mean = 65.1 years) that arrived in the emergency room in cardiac arrest from nonhypovolemic causes (i.e., no hemorrhage), and for whom no functioning IV existed. They used Jamshidi needles to establish IO access above the medial malleolus of the tibia in less than one minute. Fluid was infused under a pressure of 300 torr. Flow rates were described as 5-12 mL/min which seems very low for a well established IO access port under pressure. The IO access port was used to administer emergency drugs such as sodium bicarbonate, lidocaine, atropine, and vasopressors. They concluded that IO administration of drugs "appears to hold promise as another useful modality for adults and older children during nontraumatic resuscitations."

Chavez-Negrete (1994) used sternal IO to administer hypertonic/hyperoncotic resuscitation using hypertonic saline/dextran (HSD) in 10 patients with hemorrhagic hypotension; other patients were treated with IV HSD or IV isotonic crystalloid. This was one arm of a larger study investigating the benefit of IV administration of hypertonic/hyperoncotic resuscitation solutions. The results were the same (beneficial) as those for 16 patients receiving HSD via peripheral vein, where all HSD treated patients had an effective normalization of blood pressure. Several animal studies have reported safe and effective resuscitation via the intraosseous route (Halvorsen, 1990; Dubick, 1992), but a recent report of treatment of dehydrated hemorrhaged swine with multiple IO infusions of HSD resulted in muscle necroses some days after treatment (Alam, 2002). In light of the recent regulatory approval of HSD in most NATO countries, further research is warranted and until then caution on IO delivery of hypertonic fluids is in order.

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Table 3 Case Reports and Trials of Adult IO vascular access

Authors	Devices	Subjects/Study	Conclusions
Tocantins &			
O'Neill,	Stylet-trephen		
1940 & 1941	needle, sternum	14 & 52 patients	Effective
			Effective, osteomyelitis was
Quilligan &	Trocared needle,	Referenced more than 800 adult	number one complication,
Turkel, 1946	sternum	and pediatric cases	<2%
		22 nonhypovolemic ER patients	
	Jamshidi, Medial	- cardiac arrest. Fluids -drugs	>80% success in <1 min; few
Iserson, 1989	Malleolar IO	infused under pressure (300 torr).	complications
Chavez-			
Negrete.,	14 gauge needle,	10 patients GI bleeding 250 ml	Effective initial treatment of
1991	Sternal IO	HSD plus 2.3 + L crystalloid;	hemorrhagic shock.
Glaeser et	Jamshidi,	142 children & 10 Adults IO	Success rate = 76%; Evidence
al., 1993	tibia	placement by EMT-Ps	of clinical response =24%
Waisman &	Bone Injection	50 adults 27 -78 years, 12 w/	
Waisman,	Gun (B.I.G.),	multiple injuries, & 7 underwent	
1997	tibia	emergency resuscitation.	Success rate = 100%
	14 gauge IO		
	trocared needle,		
Lavis, 1999	iliac crest	4 adults trauma & cardiac arrest	Successful & recommended
	FAST-1, BIG,		
	Sur-Fast,	Human Cadavers	
Calkins et	Jamshidi,	Special Ops medics placed all 4	All IO devices easy to learn &
al., 2000	Sternum & tibia	IO devices in randomized order	place; 94+% success
Mcnab et al,		50 patients	Success = 74% - first-time
2000; Susak	FAST 1,	Pilot study of FAST-1 insertion	users, 95% - experienced
et al., 2000	sternum	times, and complications.	users; Failure in "very obese"
Frascone,	FAST-1,		"underwent a successful
2003	sternum	severely burned adult patient	cardiac resuscitation"

Glaeser et al. (1993) conducted a 5-year, nonrandomized trial of patients (all ages from newborn to 102 years) to "evaluate the ability of emergency medical technician-paramedic (EMT-P) units to become and remain proficient in the performance of the intraosseous infusion procedure". The study enrolled 152 patients with EMT-P placed IO lines using the Jamshidi sternal IO needle placed in the proximal tibia. EMT-Ps made 165 attempts to place the IO needles, with a success rate of 76%. There was slightly greater success in newborns and infants than in older children. The group noted the proficiency of the EMT-Ps as high and that proficiency was maintained over the 5-year period. They also noted that the most common errors in establishing IO access were errors in landmark identification and bending of needles. They noted evidence of clinical response (to treatment through the IO port) in 28 patients.

Waisman and Waisman (1997) conducted a prospective study to determine the feasibility of using IO infusions in adults using the newly developed Bone Injection Gun (BIG) for an industry-sponsored study. This



study was done in Israel where the device was used for a number of years before regulatory approval in the US. The study had two groups, one composed of adult patients with recent, closed long-bone fractures needing surgery with regional anesthesia, and another group that required "emergency or semi-emergency vascular access" where standard IV access could not be established in reasonable time. The study enrolled 50 patients ranging in age from 27-78 years. Seven patients required emergency resuscitation. IO placement was reported to be 100% successful and there were no complications. The authors emphasize the need to consider the intraosseous route for rapid vascular access.

Lavis (1999) reported on use of adult IO access in 4 patients suffering from either cardiac arrest or traumatic injuries. Notably they used a 14 gauge trocared needle to enter the iliac crest and reported success with access and delivery of fluid and drugs.

Macnab et al. (2000) studied the first 50 uses of the FAST 1 IO device (Pyng Medical) in the sternum of adults. Six emergency departments and 5 prehospital sites, in both Canada and the U.S., provided data for this industry-sponsored study. Data included success rates, insertion times, and complications. "The overall success rate for achieving vascular access with the system was 84%. Success rates were 74% for first-time users, and 95% for experienced users." Failure to achieve placement occurred most often due to obesity and the thick tissue layer overlying the IO placement site – the sternum. Maximum flow rates for gravity drip infusions were 80 ml/min and 150 ml/min for bolus injections by syringe. Syringes can generate pressures in the several hundred torr range. No complications were reported in a follow-up study 2 months later. The group concluded that the FAST 1 IO system "may provide rapid, safe vascular access and may be a useful technique for reducing unacceptable delays in the provision of emergency treatment."

Calkins et al. (2000) conducted one of the few independent studies comparing different adult IO devices. They determined the ability of 31 military Special Operations medical personnel (Army, Navy and Air Force) to learn and use IO as a means of rapid vascular access in cadavers. They also compared four commercially available IO devices, the Jamshidi, the Sur-Fast, the BIG and the Fast-1 (see Table 3). Training was comprised of lecture and videotape. Each study subject used all four IO devices. A post-study questionnaire revealed that each device was easy to learn. Placement success ranged from 94-97% and though all of the devices were acceptable, the study did not recommend one device over the others. The Bone Injection Gun was a favorite of the medics (65%) with the Jamshidi coming in second at 52%.

Finally, Frascone et al. (2003) provide a case report describing the successful placement of a sternal IO device in a severely burned patient, through burned skin. Since burns have been considered a contraindication, this single patient case report is significant. The authors state that the patient was "in full arrest" and successfully underwent cardiac resuscitation with the aid of the device. No complications were described.

Overall then it appears that placement and use of a variety of IO devices is associated with a high likelihood of success, and few and minor complications are encountered. Studies addressing the teaching of IO use describe the ease with which students of various training levels learn to become proficient in the placement and use of IO devices, and the retention of that proficiency over several years.

The extensive literature and use of IO vascular access resulted in a change of the standard of care for treating pediatric emergencies. The approach was validated by adoption into the American Heart Association's Pediatric Advance Life Support guidelines. The American military had a special need for a better means of adult vascular access as medics and corpsmen were trained in starting IV, but did not get the continual clinical practice required to maintain competency. When faulty competence is coupled with the

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difficult environments faced in combat casualty care, the need for a faster, more reliable and foolproof system of vascular access was apparent. The National Academy of Science's Institute of Medicine organized a select panel to make recommendations for fluid resuscitation and they advocated the adoption of IO use for field resuscitation (Pope et al., 1999). Additionally, several recent reviews have discussed the special needs of the military for IO vascular access (Calkins, 2000; Dubick & Holcomb, 2000; Holcomb, 2001; Dubick and Atkins, 2003). Whether the use is military or civilian, it appears clear that IO use in adults is well justified in the prehospital environment. It also appears that emergency departments worldwide are beginning to consider, if not embrace such technology for use in adults.

Future Trends in Intraosseous Use

For all of the promise for IO use indicated above, there remain reasonable concerns regarding the efficacy and safety of IO use as an alternate route for vascular access. In the critically injured or ill, time matters and therapy must be prompt and sustained until definitive care is provided. Future work on how well the IO route holds up to continuous and intermittent use over several hours is needed. The relative safety and efficacy of the tibial IO sites versus sternal sites need to be examined. Direct comparison of all the currently FDA approved adult IO access devices needs comparison in randomized trials if possible and balanced cohort trials if not. The range of infusion rates possible in the tibia and sternum need to be determined and how this can be increased with pressurized fluids when large volume therapy is needed.

In the special case of exposure to chemical weapons agents (nerve toxins, mustard agents, etc.), IO use provides a very rapid vascular access. Moreover, the ease of use and the ease of learning the techniques of IO use will make IO use available to a wider variety and greater numbers of "first responders" – a true force multiplier. In the response to exposure to chemical weapons agents, it takes several minutes after IM autoinjector delivery of nerve gas antidotes to reach pharmacologically effective levels with an intact circulation. This contrasts with the rapid onset of symptoms following exposure. Treatment of chemical weapon casualties may need direct vascular entry of drugs such as can be accomplished via the IO route. A recent simulation was designed to test the impact of using IO delivery of nerve gas antidotes to mass casualties with medical personnel in full protective gear (Vardi, 2004). IO and IV delivery of antidotes can be life saving compared to IM delivery, as it takes 10-20 minutes longer for pharmacologically effective concentrations to be reached in a normal or healthy circulation (Sidell, 1971). The simulated survival rate with physicians equipped with BIG IO needle injectors was 73.4%, while with standard treatment modalities, IM injectors, the survival rate was 3.3%. One wonders if the use of a self contained IO drug injector would be most efficacious for that scenario.

A recent chapter in the American Heart Associations 2003 ACLS textbook (pp. 214-218) emphasizes the potential for adult IO access and infusion for treatment of prehospital cardiac emergencies in conjunction with AEDs for earlier treatment of cardiac arrest. However, the authors are critical because the peer literature is mostly industry driven with an emphasis on "competitive data" such as procedure or access time and time to infusion. Formal guideline recommendations by the American Heart Association await higher levels of evidence. There are virtually no randomized trials or reports or even *a priori* designed studies of clinical outcomes. Questions addressing the impact of any speed advantage on outcomes need to be addressed. Can new IO technologies put more advanced medical capability in the hands of First Responders? We agree that more evidence-based data is needed. The AHA, the NIH and US Army need to encourage such efforts through specific requests for proposals as was done in the recent PULSE initiative by the National Heart, Lung and Blood Institute in collaboration with the US Army (Becker et al, 2002).

One might look at the use of IO access in adults as a future trend, but as the historical literature points out, this in itself is not new. A recent article exploring other intraosseous sites (clavicle, iliac crest, etc.;



Iwama et al., 1994) in adults indicates that alternate or more effective IO sites are still the subject of investigation. Even the use of bony sites without traditional medullary cavities are being explored as potential IO sites (McCarthy et al., 2003) in the critically ill adult. Greater use of IO devices for the initial administration of time-critical drugs or biologics will likely be the subject of future investigation. IO technology is being used to validate IO sites as reasonable for blood chemistry analyses (Johnson et al., 1999; Hurren, 2000), and one group, so far, is giving anesthesia through IO sites (Waisman et al., 1995). Moreover, the use of the IO device as a stable platform for incorporation of physiologic or pharmacologic sensors represents another possible new consideration IO technology. Another new effort that will likely refine IO technology will be greater emphasis on clinical, outcomes-based research. This will represent a move away from the "classic" speed-of-procedure investigations characteristic of much of the scientific literature. But the biggest effort for technical investigation will likely be using the mechanically stable IO platform as a portal of choice for closed-loop fluid- and drug-based resuscitative therapy.

CONCLUSIONS - POSSIBLE BENEFITS FOR NATO ALLIES

There has been renewed interest in military applications for IO vascular access, especially within the U.S Army and Special Operations Forces (Calkins, 2000; Dubick & Holcomb, 2000; Holcomb, 2001; Dubick and Atkins, 2003). Such interest is due in part to the recognition of the threats caused by delays in establishing effective vascular access, particularly under difficult field conditions of combat. For the casualties of military trauma, the IO route is particularly attractive for many reasons: battlefield visibility and lighting can be impaired; medics may be wearing heavy globes and MOPP suits, making IV access more difficult; medics and corpsmen may have less than ideal IV skills, since they have less ongoing clinical trauma experience than civilian paramedics.

The available literature suggests that IO device insertion is generally more rapid than establishing traditional IV access, and considerably faster than establishing a venous cutdown. These times should only get faster as technologies and teaching, practice and use policies are refined. This means more casualties will benefit more quickly from resuscitative fluids or drugs, and potentially, more lives will be saved. Greater use of the technology and greater confidence in its efficacy may eventually remove some of the restrictive barriers now faced by IO use, namely, initial and varying delays while often futile attempts at IV insertion fail, or restriction of use to certain classes of healthcare workers. It is encouraging to note that the rate for various possible complications is extremely low and often mitigated with proper training and technique. While the data indicate greater current acceptance of this technique for pediatric than adult use, adults are at equal or greater risk for time-critical events necessitating intraosseous vascular access. The literature further teaches us that training in the actual use of intraosseous devices is often modest and that this may be the largest factor limiting its use and its success when used. The lack of overall awareness of the technique, lack of proper training tools, a lack of acceptance by training teams or an institutional policy unfriendly to widespread use of IO access all contribute to lethargic adoption of IO use for adult populations. However, adult IO access training will expand due to the greater emphasis of authors of papers on IO use in adults and the support now emerging from institutional groups such as the Institute of Medicine, the American Heart Association and the military. Continued refinement of the technology and greater acceptance of its role in pre-hospital care will lead to reduced logistic burdens for IO devices, compared with the technology in use today. All of these changes will benefit pre-hospital, emergency care and the logistic concerns associated with both, several of the forward medical treatment issues about which NATO has great concern. Finally, Since the use of IO technologies is taught in the U.S., Canada, the U.K., Germany, France, the Netherlands and elsewhere, the countries of the NATO alliance already have a firm foundation for greater adoption and wider use of IO and IOI applications.

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